

Title 19 - DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30 - Division of Regulation and Licensure
Chapter 40 – Comprehensive Emergency Medical Services Systems Regulations

PROPOSED REGULATIONS

19 CSR 30-40.XXX Standards for STEMI Center Designation.

PURPOSE: This amendment defines the requirements that a facility must meet to be designated as a STEMI Center.

EDITOR'S NOTE: I-R, II-R, III-R or IV-R after a standard indicates a requirement for level I, II, III, or IV STEMI center respectively. I-IH, II-IH, III-I, or IV-IH after a standard indicates an in-house requirement for level I, II, III, or IV STEMI center respectively. I-IA, II-IA, III-IA, IV-IA indicates an immediately available requirement (within 20 minutes) for level I, II, III or IV STEMI center respectively. I-PA, II-PA, III-PA, or IV-PA indicates a promptly available (within 30 minutes) requirement for level I, II or III STEMI center respectively.

PUBLISHER'S NOTE: The Secretary of State has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome and expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) General Standards for STEMI Center Designation.

- (A) The hospital board of directors, administration, medical staff and nursing staff shall demonstrate a commitment to quality STEMI care. Methods of demonstrating the commitment shall include, but not be limited to, a board resolution that the hospital governing body agrees to establish policy and procedures for the maintenance of services essential for a STEMI center; assure that all STEMI patients will receive medical care at the level of the hospital's designation; commit the institution's financial, human and physical resources as needed for the STEMI program; and establish a priority admission for the STEMI patient to the full services of the institution. (I-R, II-R, III-R, IV-R)
- (B) STEMI centers shall agree to accept all STEMI patients appropriate for the level of care provided at the hospital, regardless of race, sex, creed or ability to pay. (I-R, II-R, III-R, IV-R)
- (C) To be designated a Level I STEMI PCI Center, a center will meet the following criteria:
 - 1. Total number of elective PCI per year per center of four hundred (400) or more.
 - 2. Primary PCI per year per center greater than forty nine (49)
 - 3. Coronary Artery Bypass Graft capability available 24/7. (I-R/PA)
- (D) To be designated a Level II STEMI PCI Center, a center will meet the following criteria:
 - 1. Total number of elective PCI per year per center of two hundred (200) or more.
 - 2. Primary PCI per year per center greater than thirty six (36)
 - 3. If a center does not meet the two hundred (200) or more elective PCI volume, but does meet specified quality measures and benchmarks, it may substitute those for the elective volume.
- (E) The hospital shall demonstrate evidence of a STEMI program that provides the STEMI team with appropriate experience to maintain skill and proficiency in the care of STEMI patients. Such evidence shall include, meeting of continuing education unit requirements by all professional staff, documented regular attendance (all core cardiologists and liaison representation from

- cardiovascular surgeons, emergency medicine physicians and anesthesiologists) at STEMI program performance improvement and patient safety program meetings, documentation of continued experience as defined by the STEMI medical director in management of sufficient numbers of STEMI patients to maintain skill levels, and outcome data on quality of patient care as identified for study by EMS region. Regular attendance shall be defined by each STEMI service, but shall be not less than fifty percent (50%) of all meetings. The STEMI medical director must ensure and document dissemination of information and findings from the peer review meetings to the non-core surgeons on the STEMI call roster.
1. The STEMI team shall be available 24/7 and consists of physicians experienced in diagnosing and treating cardiovascular disease and STEMI and at least one other health care professional credentialed in STEMI as determined by the hospital. (I-R/PA, II-R/PA, III-R/PA, IV-R)
 2. The Cardiac Cath team shall be available 24/7 and consist of, but not limited to: (I-R/PA, II-R/PA)
 - A. Cardiologist experienced in diagnosing and treating STEMI
 - (1) Interventional cardiologist shall maintain seventy five (75) or more PCI per physician per year.
 - B. Other health care professionals as deemed necessary
 3. The multidisciplinary team shall include an appropriate representative from hospital administration, emergency medical services, emergency department, ICU, cardiac cath lab, pharmacy, laboratory, radiology, cardiac unit, cardiac rehabilitation and discharge planning. (I-R, II-R, III-R, IV-R)
- (F) There shall be a lighted designated helicopter landing area at the STEMI center to accommodate incoming medical helicopters. (I-R, II-R, III-R, IV-R)
1. The landing area shall serve solely as the receiving and take-off area for medical helicopters and shall be cordoned off at all times from the general public to assure its continual availability and safe operation. (I-R, II-R, III-R, IV-R)
 2. The landing area shall be on the hospital premises no more than three (3) minutes from the emergency room. (I-R, II-R, III-R, IV-R)
- (G) The hospital shall appoint a board-certified[cardiologist] to serve as the STEMI medical director. (I-R, II-R, III-R, IV-R)
1. There shall be a job description and organization chart depicting the relationship between the STEMI medical director and other services. (I-R, II-R, III-R, IV-R)
 2. The STEMI medical director shall be a member of the cath lab team call roster. (I-R, II-R)
 3. The STEMI medical director shall be responsible for the oversight of the education and training of the medical and nursing staff in STEMI care. (I-R, II-R, III-R, IV-R)
 4. The STEMI medical director shall document a minimum average of ten (10) hours of continuing medical education (CME) in acute coronary syndrome every three years. (I-R, II-R, III-R, IV-R)
 5. The STEMI medical director shall participate in the STEMI center's research and publication projects. (I-R)
- (H) There shall be a STEMI program manager who is a registered nurse or qualified individual. (I-R, II-R, III-R, IV-R)
1. There shall be a job description and organization chart depicting the relationship between the STEMI program manager and other services. (I-R, II-R, III-R, IV-R)
 2. The STEMI program manager shall document a minimum average of ten (10) hours of continuing nursing education in cardiovascular disease every three years and attend one

national or regional meeting every other year that focuses on some aspect of cardiovascular disease. (I-R, II-R, III-R, IV-R)

3. The STEMI program manager shall participate in the formal Quality Improvement program.
- (I) All members of the Cath Lab team call roster and emergency medicine physicians shall document a minimum average of eight (8) hours of CME in cardiovascular disease every three years. (I-R, II-R, III-R)
- (J) There shall be a specific and well-organized system for the Emergency Department to rapidly notify and activate the Cath Lab team. (I-R, II-R)
- (K) Cardiac rehabilitation services shall be directed by a physician with board certification in physical medicine and rehabilitation or by other properly trained individuals (i.e., physician experienced in cardiac rehabilitation.) (I-R, II-R)
- (L) The hospital shall demonstrate that there is a plan for adequate post-discharge follow-up on STEMI patients, including rehabilitation and repatriation if indicated. (I-R, II-R, III-R)
- (M) A Missouri STEMI registry shall be completed on each STEMI patient and meets the following criteria: Includes at least one (1) code within the range of the following diagnostic codes as defined in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9)-(CM) XXX-XXX which is incorporated by reference in this rule as published by the Centers for Disease Control and Prevention in 2006 and is available at National Center for Health Statistics, 1600 Clifton Road, Atlanta, Georgia 30333. This rule does not incorporate any subsequent amendments or additions and must include one of the following criteria: hospital admission, or patient transfer out of facility or death resulting from the STEMI (independent of hospital admission or hospital transfer status.) The registry shall be submitted electronically in a format defined by the Department of Health and Senior Services. Electronic data shall be submitted quarterly, ninety (90) days after the quarter ends. The STEMI registry must be current and complete. A patient log with admission date, patient name, and diagnosis must be available for use during the site review process. Information provided by hospitals on the STEMI registry shall be subject to the same confidentiality requirements and procedures contained in section 192.067, RSMo. (I-R, II-R, III-R, IV-R)
- (N) The hospital shall have a one-call Cath lab team activation protocol that establishes the criteria used to rank STEMI patients according to time of symptom onset and identifies the persons authorized to notify Cath lab team members when a suspected STEMI patient is en route or has arrived at the STEMI center. (I-R, II-R)
 1. The one-call Cath lab team activation protocol shall provide for immediate notification and response requirements for Cath lab team members when a suspected STEMI patient is en route to the STEMI center. (I-R, II-R)
 - A. Hospital shall have a protocol for “One Call Cath lab activation by EMS” at time of EMS STEMI identification. (I-R, II-R)
- (O) The hospital shall have a one-call transfer protocol to the PCI center that establishes the criteria used to rank STEMI patients according to time of symptom onset and identifies the persons authorized to notify the PCI center. (III-R, IV-R)
- (P) The hospital shall have a plan to notify an organ or tissue procurement organization and cooperate in the procurement of anatomical gifts in accordance with the provisions in section 194.233, RSMo. (I-R, II-R, III-R)

(2) Hospital Organization Standards for STEMI Center Designation.

- (A) There shall be a delineation of privileges for the cardiologists/cardiothoracic surgeons made by the medical staff credentialing committee. (I-R, II-R, III-R)

- (B) All members of the Cath lab team call roster shall comply with the availability and response requirements per the hospital policy. If not on the hospital premises, Cath lab team members who are promptly available shall carry electronic communication devices at all times to permit contact by the hospital and shall respond promptly to a contact by the hospital. (I-R, II-R, III-R)
- (C) Physicians who are board-certified, or board-admissible and who are credentialed by the hospital for STEMI care shall be on the STEMI center staff and be available as indicated.
 - 1. Cardiology—(I-R/PA, II-R/PA, III-R/PA)
 - [A. The cardiology staffing requirement may be fulfilled by a senior cardiology resident credentialed in cardiology.
 - B. The cardiologist shall be immediately available and in attendance with the patient when a cardiology resident is fulfilling availability requirements.]
 - 2. Cardiac/thoracic surgery—[I-R/PA]
 - A. In a level I STEMI center call rosters providing back-up cardiovascular coverage will be maintained.
 - 3. Emergency medicine—(I-R/IH, II-R/IH, III-R/IH, IV-IA)
 - 4. Internal medicine—(I-R/PA, II-R/PA, III-R /PA)
 - 5. Pathology—(I-R, II-R)
 - 6. Radiology—(I-R/PA, II-R/PA, III-R/PA)
 - 7. Anesthesiology—(I-IH, II-PA)
 - A. Anesthesiology staffing requirements may be fulfilled by anesthesiology residents or certified registered nurse anesthetists (CRNA), or anesthesia assistants capable of assessing emergent situations in STEMI patients and of providing any indicated treatment including induction of anesthesia. When anesthesiology residents, anesthesia assistants or CRNA's are used to fulfill availability requirements, the staff anesthesiologist on call will be advised and promptly available and present for all operative interventions and emergency airway conditions. The CRNA may proceed with life preserving therapy while the anesthesiologist is en route under the direction of the cardiologist/cardiovascular surgeon, including induction of anesthesia.

(3) Standards for Special Facilities/Resources/Capabilities for STEMI Center Designation.

- (A) The hospital shall meet emergency department standards for STEMI center designation.
 - 1. The emergency department staffing shall ensure immediate and appropriate care of the STEMI patient. (I-R, II-R, III-R, IV-R)
 - A. The physician director of the emergency department shall be board-certified or board-admissible in emergency medicine. (I-R, II-R)
 - B. There shall be a physician trained in STEMI care current in cardiovascular CME and who maintains annual STEMI competencies in the emergency department twenty-four (24) hours a day (I-R, II-R, III-R)
 - C. There shall be written protocols defining the relationship of the emergency department physicians to other physician members of the Cath lab team. (I-R, II-R)
 - D. All registered nurses assigned to the emergency department shall be credentialed in STEMI nursing by the hospital within one (1) year of assignment. (I-R, II-R, III-R, IV-R)
 - E. Registered nurses shall document a minimum of eight (8) hours of STEMI-related continuing nursing education per year. (I-R, II-R, III-R)
 - F. Registered nurses shall maintain core competencies yearly as determined by the hospital. (I-R, II-R, III-R, IV-R)

- G. The emergency department shall have written care protocols for triage and treatment of acute STEMI patients available to ED personnel and should be reviewed and revised annually. (I-R, II-R, III-R, IV-R)
 - 2. Equipment for resuscitation and life support with age appropriate sizes shall include the following:
 - A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, sources of oxygen and mechanical ventilator I-R, II-R, III-R, IV-R (except mechanical ventilator);
 - B. Suction devices I-R, II-R, III-R, IV-R;
 - C. Electrocardiograph, cardiac monitor and defibrillator I-R, II-R, III-R, IV-R;
 - D. Central line insertion equipment-I-R, II-R, III-R;
 - E. All standard intravenous fluids and administration devices including intravenous catheters I-R, II-R, III-R, IV-R;
 - F. Sterile surgical sets for procedures standard for the emergency department -I-R;
 - G. Drugs and supplies necessary for emergency care I-R, II-R, III-R, IV-R;
 - H. Two-way radio linked with emergency medical service (EMS) vehicles-I-R, II-R, III-R, IV-R;
 - I. Equipment necessary to receive EMS prehospital EKG—I-R, II-R, III-R, IV-R
 - I End-tidal carbon dioxide monitor--I-R, II-R, III-R
 - J. Temperature control devices for patient, parenteral fluids and blood-I-R, II-R, III-R;
 - K. Rapid infusion system for parenteral infusion-I-R, II-R.
 - 3. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule. (I-R, II-R, III-R, IV-R)
- (B) The hospital shall have a designated ICU for STEMI center designation. (I-R, II-R, III-R)
- 1. There shall be a designated medical director for the ICU. (I-R, II-R, III-R)
 - 2. A physician who is not the emergency department physician shall be on duty in the ICU or available in-house twenty-four (24) hours a day in the STEMI center. (I-R, II-R, III-R)
 - 3. The minimum registered nurse/patient ratio used shall be one to one (1:1) or one to two (1:2). (I-R, II-R, III-R)
 - 4. Registered nurses shall have a minimum of eight (8) hours of STEMI-related continuing nursing education per year. (I-R, II-R, III-R)
 - 5. Registered nurses shall maintain core competencies yearly as determined by the hospital. (I-R, II-R, III-R, IV-R)
 - 6. There shall be beds for STEMI patients or comparable level of care provided until space is available in ICU. (I-R, II-R, III-R)
 - 7. Equipment for resuscitation and to provide life support for the STEMI patient shall be available for the intensive care unit. This equipment shall include, but not be limited to:
 - A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, and a mechanical ventilator (I-R, II-R, III-R)
 - B. Oxygen source with concentration controls-(I-R, II-R, III-R)
 - C. Cardiac emergency cart, including medications (I-R, II-R, III-R)
 - D. Electrocardiograph, cardiac monitor and defibrillator (I-R, II-R, III-R)
 - E. Electronic pressure monitoring and pulse oximetry (I-R, II-R, III-R)
 - F. End-tidal carbon dioxide monitor and mechanical ventilators (I-R, II-R, III-R)
 - G. Patient weighing devices (I-R, II-R, III-R)
 - H. Drugs, intravenous fluids and supplies (I-R, II-R, III-R)

- [I. Intracranial pressure monitoring devices (I-R, II-R)]
- 8. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule. (I-R, II-R, III-R)
- (C) The hospital shall meet post-anesthesia recovery room (PAR) standards for STEMI center designation.
 - 1. Registered nurses and other essential personnel who are not on duty shall be on call and available within **sixty (60)** minutes. (I-R)
 - 2. Registered nurses shall maintain core competencies yearly as determined by the hospital. (I-R, II-R, III-R, IV-R)
 - 3. Equipment for resuscitation and to provide life support for the STEMI patient shall include, but not be limited to:
 - A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes of all sizes, bag-mask resuscitator, sources of oxygen and mechanical ventilator-(I-R)
 - B. Suction devices (I-R)
 - C. Electrocardiograph, cardiac monitor and defibrillator (I-R)
 - D. All standard intravenous fluids and administration devices, including intravenous catheters (I-R)
 - E. Drugs and supplies necessary for emergency care (I-R)
- (D) Cath lab capabilities for STEMI center designation shall include:
 - 1. Angiography with interventional capability available twenty-four (24) hours a day (I-R, II-R)
 - 2. Registered nurses shall document a minimum of eight (8) hours of STEMI-related continuing nursing education per year. (I-R, II-R, III-R)
 - 3. Registered nurses shall maintain core competencies yearly as determined by the hospital. (I-R, II-R, III-R, IV-R)
 - 4. Resuscitation equipment available to the cath lab-(I-R, II-R)
 - 5. There shall be documentation that all equipment is checked according to the hospital preventive maintenance schedule. (I-R, II-R)
- (E) The Cardiac inpatient unit of a designated STEMI center shall have the following personnel and equipment: (I-R, II-R, III-R)
 - 1. Registered nurses and other essential personnel on duty twenty-four (24) hours a day (I-R, II-R, III-R)
 - 2. Registered nurses shall document a minimum of eight (8) hours of STEMI-related continuing nursing education per year. (I-R, II-R, III-R)
 - 3. Registered nurses shall maintain core competencies yearly as determined by the hospital. (I-R, II-R, III-R, IV-R)
 - 4. Equipment for resuscitation and to provide support for the injured patient including, but not limited to:
 - A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes of all sizes, bag-mask resuscitator and sources of oxygen (I-R, II-R, III-R)
 - B. Suction devices (I-R, II-R, III-R)
 - C. Electrocardiograph, cardiac monitor and defibrillator (I-R, II-R, III-R)
 - D. All standard intravenous fluids and administration devices and intravenous catheters (I-R, II-R, III-R)
 - E. Drugs and supplies necessary for emergency care (I-R, II-R, III-R)
 - 5. Documentation that all equipment is checked according to the hospital preventive maintenance schedule (I-R, II-R, III-R)

- (F) The operating room personnel, equipment and procedures of a STEMI center shall include, but not be limited to:
1. An operating room adequately staffed in-house twenty-four (24) hours a day (I-R)
 2. Equipment including, but not limited to:
 - [A. Operating microscope-(I-R);]
 - B. Thermal control equipment for patient, parenteral fluids and blood (I-R)
 - C. X-ray capability- (I-R)
 - D. Instruments and equipment necessary for CABG-(I-R)
 - E. Monitoring equipment-(I-R)
 3. Documentation that all equipment is checked according to the hospital preventive maintenance schedule-I-R;
- (G) The following clinical laboratory services shall be available twenty-four (24) hours a day:
1. Standard analyses of blood, urine and other body fluids-(I-R, II-R, III-R, IV-R)
 2. Blood typing and cross-matching—(I-R, II-R, III-R, IV-R)
 3. Coagulation studies—(I-R, II-R, III-R, IV-R)
 4. Comprehensive blood bank or access to a community central blood bank and adequate hospital blood storage facilities- (I-R, II-R, III-R)
 5. Blood gases and pH determinations- (I-R, II-R, III-R, IV-R)
 6. Blood chemistries (I-R, II-R, III-R, IV-R).
- (H) The hospital shall have cardiac rehabilitation or a written network agreement for the provision of cardiac rehabilitation. (I-R, II-R, III-R, IV-R)
- (I) There shall be documentation of adequate support services in assisting the patient's family from the time of entry into the facility to the time of discharge. (I-R, II-R, III-R)
- (J) The hospital shall have a rapid transfer process in place to a higher level of STEMI care. (II-R, III-R, IV-R)

(4) Standards for Programs in Performance Improvement Safety Program, Outreach, Public Education and Training for STEMI Center Designation.

- (A) There shall be an ongoing performance improvement and patient safety program designed to objectively and systematically monitor, review and evaluate the quality, timeliness and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems. (I-R, II-R, III-R, IV-R)
- (B) The following additional performance improvement and patient safety measures shall be required as part of a STEMI/AMI CQI process :
1. All STEMI centers shall collect, trend and report electronically to the Department key data indicators as identified by Department of Health and Senior Services. (I-R, II-R, III-R, IV-R)
 2. STEMI PCI centers shall attain and monitor device or balloon time within ninety (90) minutes from first medical contact or prehospital EKG STEMI diagnosis 75% of the time. (I-R, II-R)
 3. STEMI centers shall deliver and monitor thrombolytics within thirty (30) minutes from first medical contact or Prehospital EKG STEMI diagnosis (75% to 80%) (III-R, IV-R)
 4. Regular reviews of all STEMI-related deaths—(I-R, II-R, III-R, IV-R)
 5. A regular morbidity and mortality review, at least quarterly-(I-R, II-R, III-R, IV- R)
 6. A regular multidisciplinary STEMI meeting that includes representation of all members with minutes of the meetings to include attendance, adherence to the STEMI protocol and findings-(I-R, II-R, III-R, IV-R);
 7. Regular reviews of the reports generated by the Department of Health and Senior Services from the Missouri STEMI registry (I-R, II-R, III-R, IV-R)

8. Regular reviews of pre-hospital STEMI care including inter-facility transfers (I-R, II-R, III-R, IV-R)
 9. Participation in EMS regional system as established by the Department of Health and Senior Services (I-R, II-R, III-R, IV-R)
 10. STEMI patients remaining greater than sixty minutes prior to transfer will be reviewed as a part of the performance improvement and patient safety program. I-R, II-R, III-R, IV-R.
 11. The receiving hospital shall provide and monitor timely feedback (recommend within seventy two hours (72)) to sending hospitals/EMS providers. (I-R, II-R)
 12. Review and monitor the core competencies of the physicians, practitioner and nurses. (I-R, II-R, III-R, IV-R)
- (C)An cardiology outreach program shall be established to assure twenty-four (24) hour availability of telephone consultation with physicians in the outlying region. (I-R, II-R)
- (D)A public education program shall be established to promote STEMI prevention and signs and symptoms awareness and to resolve problems confronting the public, medical profession and hospitals regarding optimal care. (I-R, II-R, III-R)
- (E) The hospital shall be actively involved in local and regional EMS systems by providing training and clinical resources. (I-R, II-R, III-R, IV-R)
- (F)There shall be a hospital-approved procedure for credentialing nurses in STEMI care. (I-R, II-R, III-R, IV-R)
1. All nurses providing care to STEMI patients and assigned to the emergency department or ICU shall complete a minimum of eight (8) hours of STEMI nursing courses to become credentialed in STEMI care. (I-R, II-R, III-R)
 2. The content and format of any STEMI nursing courses developed and offered by a hospital shall be developed in cooperation with the STEMI medical director. A copy of the course curriculum used shall be filed with the Section for Health Standards and Licensure (HSL). (I-R, II-R, III-R)
- (G) A hospital diversion protocol must be maintained in accordance with state regulations. This protocol is designed to allow best resource management within a given area. This protocol must contain a defined performance improvement and patient safety process to review and validate established criteria within that institution. Hospital diversion information must be maintained to include date, length of time and reason for diversion.
- (5) Standards for the Programs in STEMI Research for STEMI Center Designation.**
- (A) The hospital and its staff shall support a research program in STEMI as evidenced by any of the following: (I-R)
1. Publications in peer reviewed journals;
 2. Reports of findings presented at regional or national meetings;
 3. Receipt of grants for study of STEMI care; and
 4. Production of evidence based reviews.
- (B) The hospital shall agree to cooperate and participate with the DHSS in conducting epidemiological studies and individual case studies for the purpose of developing STEMI prevention programs. (I-R, II-R, III-R, IV-R)

AUTHORITY: (to be added)

**Original authority:*

PUBLIC COST: This proposed amendment will cost state agencies or political subdivisions

PRIVATE COST: This proposed amendment will cost private entities

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with, Director, Department of Health and Senior Services, Division of Regulation

Proposed Regulations-STEMI Center Designation
May 12, 2009

and Licensure, PO Box 570, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.